

NOT FOR PUBLICATION

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

FENNEC PHARMACEUTICALS INC.,

Plaintiff,

v.

CIPLA LIMITED and CIPLA USA, INC.,

Defendants.

Civil Action No. 23-123

OPINION

July 14, 2025

SEMPER, District Judge.

THIS MATTER comes before the Court on the parties’ application for claim construction. This case arises from patent infringement litigation involving two patents: U.S. Patent No. 11,617,793 (the “’793 patent”) and U.S. Patent No. 11,964,018 (the “’018 patent”).¹ Plaintiff Fennec Pharmaceuticals Inc. (“Fennec”) owns this patent and has sued Defendants Cipla Limited and Cipla USA Inc. (collectively, “Cipla”) for patent infringement under 35 U.S.C. §§ 100, 271(a), (b), (c), (e), and (f). The parties seek construction of four terms across both the ’793 patent and ’018 patent. The parties each submitted opening and responsive claim construction briefs (ECF 132, 133, 138, 139), and the parties appeared before the Court for oral arguments on these claimed terms on May 22, 2025 (ECF 148).

¹ Plaintiff has sued the same Defendants under another patent (U.S. Patent No. 12,311,026 (the “’026 patent”)) in the case captioned *Fennec Pharmaceuticals Inc. v. Cipla Ltd. et al.*, 25-cv-05709 (D.N.J. May 27, 2025), and Plaintiff has also moved to consolidate that case with this one. The Court has granted that motion in its Opinion dated July 14, 2025, but it will not address claims in the ’026 patent until the parties have had a sufficient opportunity to brief any claim construction issues in the newly consolidated case.

I. LEGAL STANDARD

A court's determination "of patent infringement requires a two-step process: first, the court determines the meaning of the disputed claim terms, then the accused device is compared to the claims as construed to determine infringement." *Acumed LLC v. Stryker Corp.*, 483 F.3d 800, 804 (Fed. Cir. 2007). "[W]hen the district court reviews only evidence intrinsic to the patent (the patent claims and specifications, along with the patent's prosecution history), the judge's determination will amount solely to a determination of law." *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 841 (2015).

The focus of claim construction is the claim language itself:

It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude. Attending this principle, a claim construction analysis must begin and remain centered on the claim language itself, for that is the language the patentee has chosen to 'particularly point[] out and distinctly claim[] the subject matter which the patentee regards as his invention.'

Innova/Pure Water, Inc. v. Safari Water Filtration Sys., 381 F.3d 1111, 1115-1116 (Fed. Cir. 2004) (citations omitted).

The Federal Circuit has established this framework for the construction of claim language:

We have frequently stated that the words of a claim 'are generally given their ordinary and customary meaning.' We have made clear, moreover, that the ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application.

The inquiry into how a person of ordinary skill in the art understands a claim term provides an objective baseline from which to begin claim interpretation. . .

In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words. In such circumstances, general purpose dictionaries may be helpful. In many cases that give rise to litigation, however, determining the ordinary and customary meaning of the claim requires examination

of terms that have a particular meaning in a field of art. Because the meaning of a claim term as understood by persons of skill in the art is often not immediately apparent, and because patentees frequently use terms idiosyncratically, the court looks to those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean. Those sources include the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art.

Phillips v. AWH Corp., 415 F.3d 1303, 1312-1314 (Fed. Cir. 2005) (citations omitted).

II. ANALYSIS

a. The Sodium Thiosulfate Terms

The first two terms the parties ask the Court to construe are “sodium thiosulfate” (ECF 133-5 (“’793 Pat.”) claim 1; ECF 133-6 (“’018 Pat.”) claim 1) and “sodium thiosulfate is at a concentration of about 0.5 M” (’793 Pat. claim 1; ’018 Pat. claim 1).² Plaintiff proposes that “sodium thiosulfate” means “a water-soluble thiol compound with the formula $\text{Na}_2\text{S}_2\text{O}_3$.” (ECF 132 at 4.) Defendants propose that “sodium thiosulfate” means “anhydrous sodium thiosulfate that has been solubilized in an aqueous solvent.” (ECF 133 at 12.) In support of their proposed construction, Defendants argue that both the claims and the specifications of the patents limit the definition of “sodium thiosulfate” to its anhydrous form, and that Fennec limited the definition of the term during the prosecution history. (*See generally id.*) Plaintiff argues that the claims do not limit sodium thiosulfate to the anhydrous form; the specifications describe many forms of sodium thiosulfate, including and beyond the anhydrous form; and Fennec did not limit the disputed term during the prosecution of the patents. (*See generally* ECF 138.)

“When a patentee explicitly defines a claim term in the patent specification, the patentee’s definition controls.” *Martek Biosci. Corp. v. Nutrinova, Inc.*, 579 F.3d 1363, 1380 (Fed. Cir.

² In the second disputed claim term, the parties do not materially dispute the meaning of the words “is at a concentration of about 0.5 M,” so the Court will address only the meaning of “sodium thiosulfate.”

2009). Plaintiff explicitly defined the term “sodium thiosulfate” in the specifications of both patents as follows: “Sodium thiosulfate (also known as sodium hyposulfite) is a water-soluble thiol compound with the formula $\text{Na}_2\text{S}_2\text{O}_3$.” (’793 Pat. at col. 13:66-14:5; ’018 Pat. at col. 14:4-3.) The Court need look no further to determine the proper construction of the “sodium thiosulfate” claim. The patent is clear on its face that “sodium thiosulfate” means “a water-soluble thiol compound with the formula $\text{Na}_2\text{S}_2\text{O}_3$.” Despite Defendants’ arguments, nothing in the record of this case, the patents themselves, or the prosecution history allows the Court to conclude otherwise. Accordingly, Plaintiff’s proposed constructions will control as to the sodium thiosulfate terms.

b. The pH Terms

The next two terms the parties ask the Court to construe are “a pH between about 6.5 and about 8.9” (’793 Pat. claim 1; ’018 Pat. claim 1) and “a pH between about 8.6 and 8.8” (’793 Pat. claims 5, 8; ’018 Pat. claims 4, 9). For the first term, Plaintiff proposes the following construction: “the pH of the pharmaceutical composition is between 6.5 and 8.9 or an integer or fractional component that is within a variation of up to $\pm 10\%$ of pH 6.5-8.9, *i.e.*, between 6.46 and 8.95.” (ECF 132 at 11.) Defendants in turn propose the claim means “a pH between 6.5 and 8.9, plus or minus 10%.” (ECF 133 at 28.) Similarly, for the second term, Plaintiff proposes “the pH of the pharmaceutical composition is between 8.6 and 8.8 or an integer or fractional component that is within a variation of up to $\pm 10\%$ of pH 8.6-8.8, *i.e.*, between 8.56 and 8.85.” (ECF 132 at 11.) Defendant proposes “a pH between 8.6 and 8.8, plus or minus 10%.” (ECF 133 at 28.)

The crux of the dispute as to these terms is the meaning of the words “about” and “value” in the context of the pH scale. In each patent, the word “about” is defined as “any values, including both integers and fractional components that are within a variation of up to $\pm 10\%$ of the value modified by the term ‘about.’” (’793 Pat. at col. 13:47-50; ’018 Pat. at col. 13:47-50.) Both patents

are silent as to the meaning of the word “value.” Plaintiff asks the Court to construe the values presented in the claims as logarithmic measurements of the concentrations of hydronium ions (H^+) and hydroxide ions (OH^-), the molecules responsible for the effects of acidity and basicity. In Plaintiff’s view, due to the logarithmic nature of the pH scale, a 10% difference in the number of the pH scale measurement does not necessarily represent a 10% difference in the underlying value (again concentration of H^+ and OH^- ions). To account for this, they propose a construction in which the word “about” modifies not simply the number of the pH measurement, but rather the underlying concentration of ions. Plaintiff’s construction arrives at a much narrower pH range than the construction proposed by Defendants. Defendants, in turn, argue that the value modified by the word “about” is simply the face value of the numbers of the pH measurement: if the number is 6.8, they say “about 6.8” effectively means “between 6.7 and 6.9.” Hence, Defendants’ construction arrives at a much broader pH range than Plaintiff’s.

“[W]here the district court needs to consult extrinsic evidence in order to understand, for example, the background science or the meaning of a term in the relevant art during the relevant time period, and where those subsidiary facts are in dispute, courts will need to make subsidiary factual findings about the extrinsic evidence. The district judge, after deciding the factual dispute, will then interpret the patent claim in light of the facts as he has found them.” *Teva Pharms. USA*, 574 U.S. at 320. In this case, given the patents’ silence on the meaning of the word “value” and the importance of that word as it relates to the modifier “about” in the context of the pH scale, the Court finds that this is a case “where the proper claim construction cannot be reached without the aid of extrinsic evidence.” *Actelion Pharm. LTD v. Mylan Pharm. Inc.*, 85 F.4th 1167, 1173 (Fed. Cir. 2023). Further, the Court finds the extrinsic evidence presented in the expert declaration of Dr. Lisa Detter-Hoskin to be instructive. (ECF 132-1 at 16-20.) Dr. Detter-Hoskin’s exposition

makes clear that the “value” being measured by the pH scale is acidity/basicity, which in turn is a measure of the concentration of H^+ and OH^- ions. (*Id.*) As such, the Court finds that Plaintiff’s construction of the pH claims more accurately describes the way a person of ordinary skill in the art would interpret the meaning of “about” as it pertains to pH values.

III. CONCLUSION

For the reasons stated above, the Court adopts Plaintiff’s proposed constructions as to both the sodium thiosulfate claims and the pH claims. An appropriate order follows.

/s/ Jamel K. Semper
HON. JAMEL K. SEMPER
United States District Judge

Orig: Clerk
cc: Michael A. Hammer,
U.S.M.J.
Parties